2005 CHAPTERED LEGISLATION

FOOD RELATED

ASSEMBLY BILL (AB) 121 (CHAPTER 707, Statutes of 2005)

The provisions of AB 121, (Vargas), become effective January 1, 2006, and relate to lead in candy. Specifically, AB 121 will do the following:

- Requires the Office of Environmental Health Hazard Assessment (OEHHA) to establish the level of lead that is considered naturally occurring in candy products
- Requires the Department of Health Services (DHS) to test specified candies (candies containing chili or tamarind) to determine if the presence of lead exceeds the adulteration level set by OEHHA.
- Requires DHS to establish procedures for use by candy manufacturers for testing and certifying candy as being unadulterated.
- Requires DHS to notify local health departments and manufacturers when high levels of lead are found in tested candies.
- Requires DHS to retest candy with elevated lead levels, upon the request of a manufacturer, to verify that the lead no longer constitutes an adulterant. If the candies are found to be in compliance, DHS is required to issue a letter to the manufacturer stating that fact.
- Requires DHS to convene an Interagency Collaborative to serve as an oversight committee on the issue of lead in candy.
- Establishes a maximum penalty of $500 per violation for knowingly or intentionally selling lead adulterated candy and allows DHS to recover the costs for laboratory testing from the manufacturer or distributor of the adulterated candy.
- Provides that the program shall be implemented only when sufficient funding exists. The statute allows for the program to be funded in whole or in part by grant funding, civil penalties, and lab analysis cost recovery.

You may obtain the full text of the bill at:

http://www.leginfo.ca.gov/pub/bill/asm/ab_0101-0150/ab_121_bill_20051007_chaptered.html

2005 CHAPTERED LEGISLATION

ASSEMBLY BILL (AB) 1081 (CHAPTER 401, Statutes of 2005)

The provisions of AB 1081, (Matthews), become effective January 1, 2006, and will affect all food processors in California. Specifically, AB 1081 will do the following:

- Provide a 15% cost of living adjustment to Processed Food Registration (PFR) Fees. These fees have only been increased by 0.75% in the last five years. This adjustment will be effective January 1, 2006.

- Provide a $250 additional registration fee for any firm engaged in seafood or juice operations that are required to implement food safety controls under a HACCP plan pursuant to 21 CFR Part 120 or 123. The additional fee will be used to support the Food and Drug Branch's (FDB) inspection of these facilities and for the review of additional procedures and monitoring records maintained by these firms under a HACCP program. This HACCP fee will be effective January 1, 2006.

- Amend existing law to allow FDB to charge a fee for all re-inspections to ensure that violations or deficiencies are abated. The rate of reimbursement will be at $100 per hour. Should your firm require a re-inspection, you will receive a bill for these services.

- Increase the penalty for violation of an embargo to a maximum $10,000 fine and/or imprisonment for not more than one year in the county jail.

- Increase the penalty for intentionally adulterating foods, drugs, or devices or adulterating foods, drugs, or devices with the intent to cause injury, to allow prosecutors to charge the offense as a felony or a misdemeanor.

- Continue FDB's Food Safety Industry Education and Training Program for another 5 years.

- Redirect the license fees collected from the bottled and vended water program from the General Fund to the Food Safety Special Fund. This change will allow FDB to ensure that the revenue collected from these licensees is used in the administration of the water program. Water bottling and vended water facilities will not notice any change in their normal licensing procedures. This is an internal change.

You can obtain the actual text of the bill by going to:

http://www.leginfo.ca.gov/pub/bill/asm/ab_1051-1100/ab_1081_bill_20050929_chaptered.html

SENATE BILL (SB) 730 (CHAPTER 685, Statutes of 2005)

SB 730, (Speier), amends existing law to add the following Section to the California Health and Safety Code:

110827. No aquaculture, fish, or seafood product, including, but not limited to, farmed and wild caught species, shall be labeled or represented as "organic" until formal organic certification standards have been developed and implemented by the United States Department of Agriculture's National Organic Program or the California Department of Food and Agriculture.

The Legislature's intent in enacting this provision was to prevent consumers from being misled by the organic label on certain fish and seafood. The legislature is aware of the presence of mercury and other carcinogenic and reproductive toxins in certain fish and seafood products, that under current law could be labeled as organic. By enacting this provision, the legislature intends to prevent consumers from being unknowingly exposed to such compounds by their incorrect assumption that an organic seafood product would be free of such materials.

You can obtain the actual text of the bill by going to:

http://www.leginfo.ca.gov/pub/bill/sen/sb_0701-0750/sb_730_bill_20051007_chaptered.html

2005 CHAPTERED LEGISLATION

DRUG RELATED

SENATE BILL (SB) 37 (CHAPTER 673, Statutes of 2005)

SB 37, (Speier), will enact the following provisions:

- SB 37 will require the Department of Health Services (DHS) to provide the California Department of Education (CDE) the "United States Anti-Doping Agency Guide to Prohibited Substances and Prohibited Methods of Doping" (USADA Guide) before March 30, 2006. Upon receipt of the USADA Guide, CDE is to notify school districts the USADA Guide is completed and post the USADA Guide on the CDE web site. DHS also is to annually notify CDE of any amendments to the USADA Guide.

- Effective sixty days after the USADA Guide is posted on the CDE web site, SB 37 will prohibit the use of dietary supplements containing synephrine or a prohibited substance in the USADA Guide by a pupil participating in interscholastic high school sports.

- SB 37 will restrict a school from accepting a sponsorship from a manufacturer or distributor of a dietary supplement containing synephrine or a prohibited substance in the USADA Guide.

- Will prohibit the marketing, sale, or distribution of a dietary supplement containing synephrine or a prohibited substance in the USADA Guide on a school site or at a school related event. Marketing would include product advertising, providing educational materials, product promotion by a school district employee or school district volunteer, product placement, clothing or equipment giveaways or scholarships.

- SB 37 will require each high school coach, effective December 31, 2008, to have completed a specified coaching education program that includes instruction on the harmful effects associated with the use of steroids and performance-enhancing dietary supplements by adolescents.

- SB 37 will require the California Interscholastic Federation to amend its constitution and bylaws to require, as a condition of participation in interscholastic sports, that school districts, effective July 1, 2006, prohibit a pupil from participating in interscholastic high school sports unless s/he signs a pledge not to use anabolic steroids without a prescription from a licensed healthcare provider or a dietary supplement containing synephrine or a prohibited substance in the USADA Guide and his or her parent signs a notification form that acknowledges that restriction.

- SB 37 will establish the California Coaching Education Fund (CCEF Fund) in the State Treasury. Voluntary contributions can be accepted by the State Treasurer and deposited into the CCEF Fund. CCEF Funds are available upon appropriation by the Legislature pursuant to specified requirements to help offset each coach's training costs.

You can obtain the actual text of SB 37 by going to:

http://www.leginfo.ca.gov/pub/bill/sen/sb_0001-0050/sb_37_bill_20051007_chaptered.html

SENATE BILL (SB) 798 (CHAPTER 444, Statutes of 2005)

The provisions of SB 798, (Simitian), will authorize a county to establish by ordinance a voluntary program for the distribution of unused, surplus prescription medications to persons in need of financial assistance. Entities who may donate excess or surplus, unused, prescribed medications under the program are licensed skilled nursing facilities (SNFs), a pharmacy wholesaler, or a drug manufacturer. Only pharmacies that are county-owned or that contract with the county may participate in the program to dispense donated medications. If a county wishes to establish a program they must: 1) establish patient eligibility criteria; 2) ensure patients are not charged for medication provided by the program; 3) develop a drug formulary for the program; 4) ensure proper safety and management of medications collected as outlined; and, 5) ensure the privacy of the individual originally prescribed the medication.

Donated medications may: 1) not be adulterated, misbranded, or stored under conditions contrary to applicable standards; 2) not have been in the possession of a patient or any individual member of the public; and 3) not be a controlled substance.

Donated medications must be: 1) received in an unopened, tamper-evident packaging or modified unit dose containers that meet United States Pharmacopoeia (USP) standards with lot numbers and expiration dates; 2) dispensed, destroyed or returned to a reverse distributor; and, 3) maintained in the donated packaging units until dispensed. Donated medications from a SNF must have been under the control of facility staff.

Participating pharmacies must: 1) adhere to established pedigree requirements; 2) store donated drugs separate from other drug stock for inventory, accounting, and inspection purposes; and 3) keep medication acquisition and disposition records separate from other pharmacy records that comply with existing Pharmacy Law requirements.

Local and county protocols for the packaging, transporting, storing, and dispensing of medication must conform to Pharmacy Law, and, in addition, medications that require refrigeration, such as biologics, infused, or intravenously injected drugs, must be packaged, transported, stored, and dispensed at their appropriate temperature and in accordance with USP standards and Pharmacy Law:

Participants in the program, such as drug manufacturers, wholesalers, governmental entities, county owned or county-contracted pharmacies, SNFs, pharmacists or other health care professionals would be exempt, as outlined, from criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs.

You can obtain the actual text of SB 484 by going to:

http://www.leginfo.ca.gov/pub/bill/sen/sb_0751-0800/sb_798_bill_20050930_chaptered.html

2005 CHAPTERED LEGISLATION

COSMETIC RELATED

SENATE BILL (SB) 484 (CHAPTER 729, Statutes of 2005)

SB 484, (Migden), will enact the following provisions:

- SB 484 will require, beginning on January 1, 2007, the manufacturer of any cosmetic product subject to regulation by U.S. Food and Drug Administration to provide to Department of Health Services' (DHS) Division of Environmental and Occupational Disease Control (DEODC) an accurate list of their cosmetic products sold in California that contain any ingredient known to cause cancer or reproductive toxicity. Failure of a manufacturer to comply would be a misdemeanor under the Sherman Food, Drug, and Cosmetic Law.

- SB 484 will exempt cosmetic manufacturers with gross cosmetic product sales less than one million dollars from submitting lists.

- SB 484 will require chemical ingredients identified by the manufacturer as "other ingredients" and determined to be "trade secret" under federal law be considered confidential and not subject to the California Public Records Act.

- SB 484 will require cosmetic product ingredients to be identified by chemical name and Chemical Abstract Service number, and to specify the product or products in which the chemical is contained.

- SB 484 will require DEODC to verify a change in a cosmetic product ingredient and revise the manufacturer's product list information if a manufacturer notifies DEODC of a change.

- SB 484 will provide that DEODC may conduct investigations into any hazardous ingredient disclosed in submitted reports. If DEODC performs an investigation on hazardous ingredients in cosmetic products, they then may conduct worksite assessments, epidemiological studies, and exposure assessments. If DEODC finds an ingredient in a cosmetic product is potentially toxic, SB 484 mandates that those findings be referred to Division of Occupational Safety and Health to determine if appropriate actions are needed to protect exposed workers.

- SB 484 will have DEODC determine if the 54 cosmetic products found in 2004 to be in violation of the Cosmetic Ingredient Review (CIR) expert panel's recommendation of safe-use have since been adequately substantiated for safety. If DHS finds that a cosmetic product has been substantiated for safety and contains an ingredient that CIR has found not to be safe, DHS is to refer this finding to the Attorney General and FDA.

You can obtain the actual text of SB 484 by going to:

http://www.leginfo.ca.gov/pub/bill/sen/sb_0451-0500/sb_484_bill_20051007_chaptered.html